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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,186	09/21/2007	Rudolf Brenneisen	33276-US-PCT	3801

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CORPORATE INTELLECTUAL PROPERTY
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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
06/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,186	BRENNEISEN ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 8-9, 33, 36-37, and 41, drawn to a method of preparation of a medicament or nutritional formulation comprising γ-glutamyl-peptide for humans or animals.

Group 2, claim(s) 2-7, 42-44, drawn to a method of treating, testing for or preventing a disease or condition which is characterized by increased bone resorption comprising administering to a human or animal in need thereof an effective amount of γ-glutamyl-peptide.

Group 3, claim(s) 10-32, 34-35, 38-40, 45-47, drawn to a nutritional or pharmaceutical composition comprising γ-glutamyl-peptide and a nutritionally or pharmaceutically acceptable carrier.

It is noted that claims 1, 6, 8-9, 36-37 and 41 recite the language "use of γ-glutamyl-peptide." "Use" claim language is improper under U.S. practice. Thus, for the purposes of this restriction, "use of γ-glutamyl-peptide" has been interpreted as a "method of use in preparation" and "method of use in treating, testing for or preventing a disease". Accordingly, claims 1, 8-9, 36-37 and 41 have been grouped as a method of preparation, and claim 6 has been grouped as a method of use in treating, testing for or preventing claims. Should applicant choose to amend this claim to make it proper, further restriction may be required.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of a nutritional or a pharmaceutical composition comprising γ-glutamyl-peptide is taught by Kuttan et al (Biochemistry, 1974, 13(21): 4394-4400, this article is on Applicant's IDS, but a copy of the article was not provided; Examiner obtained her own copy for use). Kuttan et al teach isolation of γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide from sandal (*Santal album L.*) (see abstract). The reference teaches powder form (colorless, granular crystals, see p. 4396, left column, 1st paragraph of Results). Furthermore, the reference teaches that γ-L-glutamyl-S-(trans-l-propenyl)-L-cysteine

sulfoxide is in aqueous solutions, water (see, p. 4396, right column, "CD ABSORPTION"). Water is nutritionally and pharmaceutically acceptable carrier, therefore, the special technical feature is disclosed by Kuttan et al. Therefore, there is lack of unity of invention.

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different γ-glutamyl-peptide: γ-glutamyl-alkyl-cysteine sulfoxide (subgenus) or γ-glutamyl-alkenyl-cysteine sulfoxide (subgenus);

Different disease or condition: Paget's disease, tumor-induced bone disease or osteoporosis;

Different calcium source: for example, from paragraph [0101] from instant specification US 20080194492 A1;

Different energy source: carbohydrate (subgenus), fat (subgenus), nitrogen sources (subgenus), claims 15-17;

Different nutritionally acceptable components: vitamins (subgenus), minerals (subgenus), trace elements (subgenus), fibers (subgenus), flavors (subgenus), preservatives (subgenus), colorants (subgenus), sweeteners (subgenus), or emulsifiers (subgenus); species from paragraphs [0121]-[0124];

Different Allium: from claim 30.

5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

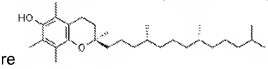
7. The claims are deemed to correspond to the species listed above in the following manner:

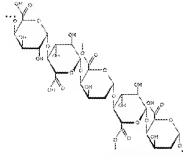
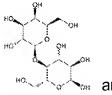
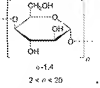
Claims 8-9, 12, 14-17, 20, 26, 30-32, 35, 43-44.

The following claim(s) are generic: Claims 1-7, 10-11, 13, 18-19, 21-25, 27-29, 33-34, 36-42, 45-47.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different γ-glutamyl-peptide are patentably independent and distinct due to their different structures. For example, alkyl (single bond) and alkenyl (double bond) are two different structures. Further, search for one would not necessarily lead to the other. Different disease or conditions are patentably independent and distinct. For example, Paget's disease is a chronic bone condition characterized by disorder of the normal bone remodeling process, thus the bone that is formed is abnormal, enlarged, not as dense, brittle and prone to breakage (see http://www.medicinenet.com/pagets_disease/article.htm). Osteoporosis is a condition characterized by the loss of the normal density of bone, resulting in fragile bone (see http://www.medicinenet.com/osteoporosis/article.htm). A person suffering from one would not necessarily suffer from the other. Further, search for one would not necessarily lead to the other. Different calcium source is patentably independent and distinct due to different due to different structures. For example, an inorganic calcium salt, calcium chloride has different structure than calcium citrate

(organic acid). Further, search for one would not necessarily lead to the other. Different nutritionally acceptable components are patentably independent and distinct due to their different structures. For example, vitamin E (also known as tocopherol) has the

structure  ; fiber pectin has the

structure  . Further, search for one would not necessarily lead to the other. Different carbohydrate source of components are patentably independent and distinct due to their different structures. For example, lactose has the structure  and maltodextrin has the structure  . Further, search for one would not necessarily lead to the other. Different fat source is patentably independent and distinct due to their different structures. For example, omega-6 fatty acids have double bond existing at the sixth carbon-carbon bond from the terminal methyl end of the carbon chain, and omega-3 fatty acids have double bond existing at the third carbon-carbon bond from the terminal methyl end of the carbon chain. Further, search for one would not necessarily lead to the other. Different nitrogen source of components are patentably independent and distinct due to their different amino acid content, leading to different structures. For example, protein hydrolysate is a mixture of amino acids prepared by splitting a protein with acid, alkali, or enzyme, and used as a fluid and nutrient replenisher (see http://medical-dictionary.thefreedictionary.com/protein+hydrolysate). Essential amino acids are Ile, Val, Leu, Phe, Trp, Thr, Met, Arg, Lys and His (see http://hyperphysics.phy-astr.gsu.edu/HBASE/organic/essam.html). Therefore, a mixture of essential amino acids and arginine could be any essential amino acids mixture and arginine. Therefore, a search for a protein hydrolysate would not necessarily lead to essential amino acid and arginine mixture. Different Alliums are patentably independent and distinct due to different sources. For example, Allium cepa is from shallots or onions. Allium sativum is from garlic. Further, search for one would not necessarily lead to the other.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

10. For any group elected, Applicant is required to elect a single disclosed species of γ-glutamyl-peptide, for example, γ -glutamyl-trans-S-propenyl-L-cysteine sulfoxide. If Group 2 is elected, Applicant is further required to elect a single disclosed species of a disease, for example, Paget's disease. If Group 3 is elected, and the nutritional composition comprises a calcium source, a carbohydrate, fat or nitrogen source, or other nutritionally acceptable components such as vitamins, minerals, trace elements (from claim 20), Applicant is further required to elect a single disclosed species of the elements. Please note, if election is not made, then this will not lead to examination of claims 13-23. If Group 3 is elected, Applicant is further required to elect a single disclosed species of Allium, for example, Allium cepa.

11. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

14. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654